U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

January 27, 2014

The Honorable Joe Manchin, III
United States Senate
Washington, DC 20510

Dear Senator Manchin:

Thank you for your letter regarding the basis for the Centers for Disease Control and Prevention's (CDC) development of a drinking water screening value for the areas of West Virginia affected by the Elk River 4-methylcyclohexanemethanol (MCHM) spill. CDC/Agency for Toxic Substance Disease Registry (ATSDR) responded immediately and continues to work closely with the state of West Virginia as well as other federal agencies.

On January 22, 2014, Dr. Vikas Kapil, our Chief Medical Officer and Associate Director for Science at the National Center for Environmental Health/ATSDR, held a phone briefing with your staff to provide additional technical details regarding our response efforts.

CDC/ATSDR is working directly with the Governor's Office and the West Virginia Bureau for Public Health on development and release of public health information to the affected community about their water. On January 17, 2014, CDC/ATSDR posted information regarding: what is MCHM, what is the acceptable level of MCHM in drinking water, how was the 1 part per million (ppm) level calculated, what studies were used in calculating the 1 ppm recommendation, and links to additional resources such as the West Virginia Governor's State Emergency Updates.

At the request of the State, CDC/ATSDR sent an Epi-Aid response team to review medical records, survey hospitals, assess disaster epidemiology capacity, and make recommendations. In response to a request from the Federal Emergency Management Agency, CDC/ATSDR deployed an environmental health advisor to provide technical support and guidance on health impacts to West Virginia.

Please find answers to your important questions enclosed. Thank you for again for your letter and for your concern about this important public health issue. CDC/ATSDR will continue to work closely with the state of West Virginia and your offices to support the public health needs of the people affected by this spill. This response is also being sent to the cosigner of your letter.

Sincerely,

Thomas R. Frieden, MD, MPH
Director, CDC
Administrator, ATSDR

Enclosure

Basis for CDC's protective standard regarding 4-methylcyclohexanemethanol (MCHM)

On Thursday, January 9, 2014, at approximately 11:00 a.m., officials became aware that a chemical known as Crude MCHM leaked into the Elk River in Charleston, West Virginia. Water from the river entered the community water system which serves approximately 300,000 people in a nine county area. The source of the leak was a chemical storage tank located approximately 1 mile from the intake to the public water system. Estimates suggest that up to 7,500 gallons of MCHM were released before the leak was fully contained. Due to the uncertainty over the chemical levels in the water supply, the Office of the Governor issued a "Do Not Use" order at 6:00 p.m. on January 9, 2014. Later that evening, the West Virginia Department of Health and Human Resources contacted CDC/ATSDR about the release and requested assistance to review water sampling data and provide a drinking water screening level for MCHM. In response to this urgent situation, a screening level of 1 part per million (ppm) was recommended. Based on the information available, a level of 1 ppm or below is not likely to be associated with any adverse health effects.

Few studies on this specialized chemical exist and most have been conducted on animals. Scientists used the limited information available about this chemical to calculate how much MCHM a person could ingest without resulting in adverse health effects. These calculations use uncertainty factors to take into account the differences between animals and people and to consider possible effects on sensitive populations. An additional factor was applied to account for the limited availability of data. Based on the application of these uncertainty factors and the available research studies, scientists recommend a screening level of 1 ppm or lower, of MCHM in drinking water.

CDC/ATSDR used the following calculation to establish a short-term screening level of 1 ppm for the MCHM spill in the Elk River:

$$DW\,Advisory \leq \frac{NOEL \times BW}{UF \times Intake}$$

Where:

- DW Advisory = Drinking Water Advisory
- NOEL = No Observed Effect Level in the experimental species (100 mg/kg/day)
- BW = Body weight of a child (10 kg)
- UF = Uncertainty factors that address differences between animals and humans (10X), address differences accounting for sensitive humans (10x), and account for weaknesses in the toxicological database (10X).
- Intake = The estimated intake from drinking water of a 10 kg child (1 liter/day).

NOEL (mg/kg/d)	BW (kg)	UF (unitless)	Intake (L/day)	DW Advisory (mg/L or ppm)
100	10	1000	1	1

Several studies from the manufacturer of MCHM were evaluated to develop the recommended level of 1 ppm. These included the Pure MCHM 28-day oral study and the Crude MCHM LD-50 oral study. CDC/ATSDR scientists then extrapolated downwards to come up with the recommendation for a level that we believe would not be associated with any adverse health effects. This methodology is widely accepted and commonly used in environmental public health and risk assessment. This same information was posted to the CDC website January 17, 2014, at http://emergency.cdc.gov/chemical/MCHM/westvirginia2014/index.asp.

The Department of Health & Human Services convened a Federal expert workgroup including scientists from the National Institute of Environmental Health Sciences and National Toxicology Program, the National Library of Medicine, the Environmental Protection Agency, and CDC/ATSDR to review all the available animal studies and the methodology for the short-term screening level calculation. This workgroup concurred that the 1 ppm short-term screening level was appropriate. A copy of this report is located on the CDC/ATSDR website at http://emergency.cdc.gov/chemical/MCHM/westvirginia2014/pdf/MCHM-Summary-Report.pdf.

The screening level of 1ppm was calculated with several factors of uncertainty which included sensitive populations, such as pregnant women.

The situation was dynamic and evolving, and CDC/ATSDR maintained constant communication with its federal partners and the state, to evaluate and adapt its public health guidance. As questions related to pregnant women were raised and considering the limited availability of data and an abundance of caution, CDC/ATSDR recommended pregnant women consider an alternative drinking water source until the chemical is at non-detectable levels in the water distribution system.

Although it is important to consider all sensitive populations, a developing fetus is considered the most vulnerable. For pregnant women, scientists generally recommend a precautionary approach, particularly when information on the reproductive health effects of a chemical is limited.

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January 27, 2014

The Honorable Shelley Moore Capito
U.S. House of Representatives
Washington, DC 20515

Dear Representative Capito:

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